PHYTO P ANTI-ITCH MOUSSE- pramoxine hydrochloride, phytosphingosine salicyloyl liquid Butler Animal Health Supply, LLC dba Covetrus North America

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Phyto P Anti-itch Mousse

Active Ingredients: Pramoxine HCl 1%, phytosphingosine salicloyl 0.05%.

Inactive ingredients: Water, glycerin, PEG-8 dimethicone, polysorbate 80, poloxamer 184, sodium lactate, hydrolyzed oat protein, fragrance, aloe barbadensis leaf extract, methylisothiazolinone.

Properties: Phyto P anti-itch mousse is formulated for the temporary relief of itching in dogs and cats without bathing. It contains pramoxine HCl, a mild numbing agent, as well as colloidal oatmeal and aloe vera to soothe irritated skin. This no-rinse mousse also contains phytosphingosine, a pro-ceramide, to help support a healthy skin barrier.

Indications: For the temporary relief of itching and skin irritations.

Directions for use: Shake well before use. Brush the fur then apply product on dry hair. Apply every 3 days for 2-3 weeks or as directed by your veterinarian.

<u>For localized application:</u> Dispense 1-2 pumps onto your palm, then apply on the targeted area(s). Massage into the skin until fully penetrated. Do not rinse, let air dry. Once dry, brush the fur again.

<u>For whole body application:</u> Dispense 1 to 2 pumps onto your palm and massage onto the skin. Repeat as many times as necessary to cover the whole body, avoiding the eyes and mouth. Do not rinse, let air dry. Once dry, brush the fur again.

Dosage:

Under 11 lbs: 1 pump per 2 lbs 11 - 88 lbs: 1 pump per 4 lbs Over 88 lbs: 1 pump per 6 lbs

Dosage may be doubled for long-haired breeds.

Cautions: For external use on dogs and cats only. Avoid contact with eyes. If eye contact occurs, rinse thoroughly and consult your veterinarian. If skin irritation occurs or increases, discontinue use and consult with your veterinarian. Wash hands after use.

Storage: Store at room temperature. Do not freeze.

Questions? (855) 724-3461

Distributed by: Covetrus North America 400 Metro Place North Dublin, OH 43017 covetrus.com

PRINCIPAL DISPLAY PANEL - 6.8 fl oz (200 mL)

covetrus

NDC 11695-7233-2

Phyto P

Pramoxine HCl 1%,

phytosphingosine salicloyl 0.05%

Anti-itch Mousse

Soothing mousse for dogs and cats

For animal use only

Keep out of reach of children

SHAKE WELL BEFORE USE

Net contents: 6.8 fl oz (200 mL)



NDC: 11695-7233-2



Pramoxine HCl 1%, phytosphingosine salicyloyl 0.05%

Anti-itch Mousse

Soothing mousse for dogs and cats

For animal use only Keep out of reach of children

SHAKE WELL BEFORE USE

Net contents: 6.8 fl oz (200 mL)

Active ingredients: Pramoxine HCl 1%, phytosphingosine salicyloyl 0.05%. Inactive ingredients: Water, glycerin, PEG-8 dimethicone, polysorbate 80, poloxamer 184, sodium lactate, hydrolyzed oat protein, fragrance, aloe barbadensis leaf extract, methylisothiazolinone.

Properties: Phyto P anti-itch mousse is formulated for the temporary relief of itching in dogs and cats without bathing. It contains pramoxine HCl, a mild numbing agent, as well as colloidal oatmeal and aloe vera to soothe irritated skin. This no-rinse mousse also contains phytosphingosine, a pro-ceramide, to help support a healthy skin barrier.

Indications: For the temporary relief of itching and skin irritations.

Directions for use: Shake well before use. Brush the fur then apply product on dry hair. Apply every 3 days for 2-3 weeks or as directed by your veterinarian.

<u>For localized application</u>: Dispense 1-2 pumps onto your palm, then apply on the targeted area(s). Massage into the skin until fully penetrated. Do not rinse, let air dry. Once dry, brush the fur again.

<u>For whole body application</u>: Dispense 1 to 2 pumps onto your palm and massage onto the skin. Repeat as many times as necessary to cover the whole body, avoiding the eyes and mouth. Do not rinse, let air dry. Once dry, brush the fur again.

Dosage:

Under 11 lbs: 1 pump per 2 lbs 11 - 88 lbs: 1 pump per 4 lbs Over 88 lbs: 1 pump per 6 lbs

Dosage may be doubled for long-haired breeds.

Cautions: For external use on dogs and cats only. Avoid contact with eyes. If eye contact occurs, rinse thoroughly and consult your veterinarian. If skin irritation occurs or increases, discontinue use and consult with your veterinarian. Wash hands after use.

Storage: Store at room temperature. Do not freeze.

Reorder #048711 Questions? (855) 724-3461 AH-048711-02 REV: 0819 Distributed by: Covetrus North America 400 Metro Place North Dublin, OH 43017 covetrus.com



F41610D-US 18-L1-v2

PHYTO P ANTI-ITCH MOUSSE

pramoxine hydrochloride, phytosphingosine salicyloyl liquid

Product Information			
Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:11695-7233
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
PRAMO XINE HYDRO CHLO RIDE (UNII: 88 AYB8 67L5) (PRAMO XINE - UNII: 068 X84E056)	PRAMO XINE HYDRO CHLO RIDE	10 mg in 1 mL			
SALICYLOYL PHYTOSPHINGOSINE (UNII: U891J4JCNH) (SALICYLOYL PHYTOSPHINGOSINE - UNII:U891J4JCNH)	SALICYLOYL PHYTOSPHINGOSINE	0.5 mg in 1 mL			

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		
PEG-8 DIMETHICONE (UNII: GIA7T764OD)		
SODIUM LACTATE (UNII: TU7HW0W0QT)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
POLOXAMER 184 (UNII: BIS92ZSF57)		
OAT (UNII: Z6J799EAJK)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11695-7233-2	200 mL in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		0 1/0 1/20 20	

Labeler - Butler Animal Health Supply, LLC dba Covetrus North America (603750329)

Registrant - Ceva Sante Animale (261126049)

Revised: 12/2019 Butler Animal Health Supply, LLC dba Covetrus North America